NFPA
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

[Docket No.00N-0120] Safety of Imported Food
65 *Federal Register* 3461-3462, January 21, 2000

Dear Sir or Madam:

- NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

NFPA submits the following comments on the docket referenced above.

GENERAL COMMENTS

- NFPA commends the Food and Drug Administration (FDA) and the US Customs Service (Customs) for developing a joint plan to address problem importers and unsafe imported foods. It has been our strong belief that a coordinated enforcement effort by FDA and Customs is an important component of increasing the effectiveness of the government's oversight of imports. Moreover, the plan contains recommendations that NFPA has made on several occasions to enhance imported food safety.

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NFPA has pointed out in meetings with FDA that, between them, FDA and Customs have ample authority under existing statutes to take actions to address a number of import-related problems. The steps now being taken to require storage in secure facilities, to destroy unsafe foods, to increase bonds and to impose civil monetary penalties for certain import violations were all identified by our analysis of current laws and regulations as options available under existing authority.

We are pleased that, in general, the agencies have developed a plan that targets the few problem importers without unfairly putting burdens on the large number of importers who consistently meet US requirements. It must be recognized that, in spite of a GAO report indicating that federal efforts to ensure the safety of imported foods are unreliable, the vast majority of foods imported into the United States are safe and enter the country legally. Nevertheless, it is true that the system is vulnerable to unscrupulous importers and that adulterated, misbranded and, on occasion, unsafe products may bypass existing controls. NFPA supports the use of deterrents to prevent importers from circumventing the controls and penalties that will discourage such conduct.

We are also pleased that FDA and Customs see the benefits of notice and/or comment procedures with regard to the initiatives outlined in the Status Report on the Presidential Initiative on the Safety of Imported Food. NFPA plans to review the guidance documents and proposed regulations and provide comments, as appropriate.

We would like to point out that, while the actions described are important in addressing import-related problems, they do not adequately address prevention of the problem. Identification of problems through sampling at ports of entry is not an effective preventive approach. We urge FDA to emphasize the development of equivalence agreements with foreign governments to assure that foods exported to the US meet US safety standards. We also urge FDA to conduct more on-site reviews of foreign systems to assure that the foreign government has the authority and has set (and is enforcing) appropriate standards and that the country has the infrastructure to justify a determination of equivalence.

Finally, while we recognize that the President directed the Secretary of Health and Human Services and the Secretary of the Treasury to address the issue of unsafe imports, we believe that actions dealing with products that come under the jurisdiction of the Department of Agriculture must also be addressed. We note that USDA was represented on the task force that developed the report and implementation plan. The plan indicates that USDA marks meat and poultry products refused entry into the US and that FDA and Customs will notify FSIS of regulatory actions (civil monetary penalties) that may include meat and poultry. The status report would be more complete if it noted how imported meat and poultry products will be addressed in all of the action areas.

COMMENTS ON ACTION AREAS

The President specifically directed FDA and Customs to take actions in six areas, outlined below with our comments.

1. Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA.

Industry supports the proposal whereby importers who have repeatedly distributed imported foods prior to FDA release or have provided false and misleading information on imported foods will be required to store shipments in secure facilities. At a February 17 public meeting to address the action plan on imports the criteria for requiring secure storage were provided; they include failure to hold product (twice in a 6 month period), failure to redeliver product for export or destruction (twice in 6 months), providing false and misleading information, or substitution of product (either prior to FDA sampling or when delivering for export or destruction). We suggest that the criterion of providing false and misleading information be modified to include "where intended to deceive," as inadvertent errors may sometimes occur. We concur with comments that options other than a Customs-bonded warehouse may be acceptable and should be investigated.

2. Destroy imported food that poses a serious public health threat.

We concur with the agencies that Customs has the authority to destroy imported foods that pose a significant risk to public health or safety. We urge the agencies to not rely solely on FDA's Class I Recall criteria as the basis for destruction, as described in the December 11, 1999 Status Report. It is imperative that the "criteria" used for determining if food poses a serious public health threat and is thus identified for destruction be defined and communicated in a transparent manner, allowing opportunity for comment by stakeholders. Many foods that would be subject to a Class I recall could be reconditioned and then released. At the February 17 public meeting, it was reported that reconditioning would be considered. The guidance materials should explicitly address situations under which products may be reconditioned. Moreover, consideration should be given to safety standards in other countries; a food that may be subject to a Class I recall in the US may not be considered unsafe in another country. For example, in the US any ready-to-eat food containing *Listeria monocytogenes* would be subjected to a Class I recall, whereas other countries may find the presence of low numbers of *L. monocytogenes* in certain products in which the organism cannot grow to be in compliance with their regulatory standards.

We urge that the agencies provide for an appeal process when FDA has determined that a product poses a health hazard serious enough to warrant destruction. We also urge prompt notification to exporters when a shipment has been identified for destruction and agree that it is appropriate, as indicated by FDA at the public meeting, to provide opportunity for the exporter to respond with a reconditioning plan. There are some occasions when an

exporter may prefer destruction to reconditioning (even when possible) and he/she should be allowed that option. (This has happened internationally because port tipping fees continue to accumulate while decisions are being made or reconditioning occurs and it becomes cheaper to destroy the product than correct the problem.) It may also be possible to convert an unsafe food to a safe animal feed or to a non-food item such as fertilizer.

The government is responsible for storage and destruction costs under Customs' forfeiture procedures. Although funds have not been specifically appropriated for destruction of seized imported foods, it is critical that Customs find the resources when FDA identifies an unsafe lot of food that cannot be reconditioned and therefore warrants destruction. Even though additional actions are being taken to prevent "port shopping," it would not be prudent to allow an unsafe food to be re-exported.

3. Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with US laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons.

NFPA supports marking or otherwise identifying non-complying imports so that rejected product cannot re-enter the country elsewhere. At the public meeting it was indicated that the agencies are considering proposing the term "Refused US" as the mark. NFPA agrees with comments made at the session on February 17 that alternative language such as "This product does not comply with US FDA requirements" may be more appropriate than "Refused US," particularly if the exporter were to seek entry into another market where the product would be deemed safe. NFPA also believes that additional information on why the product is refused is important, as product that is refused entry into the US may be perfectly acceptable elsewhere. The reason for refusal need not be marked on each container, but it should be included with the shipping papers.

4. Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States.

NFPA supports the use of third party sample collection services and outside labs as a means to expedite release of product. We recognize that there may be concerns about the accuracy of laboratory analyses when importers sample products and send them to the laboratory of their choice. We believe it is appropriate for FDA to provide guidelines for the collection and analysis of samples. Such guidance could also include performance criteria for laboratories. However, it is important that FDA consider carefully the issue of requiring laboratories to be accredited. This can be a very expensive proposition, especially when laboratories may face multiple accreditations to meet government and customer requirements. The accrediting body and the accreditor of those bodies (NACLA) must be free from undue influence from the laboratories considered for accreditation. If FDA does require accreditation, the Agency's own labs must also meet

equivalent accreditation standards. Protocols must be developed to address issues arising when there are conflicting results from an FDA laboratory and an accredited private laboratory.

5. Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States.

Imported foods are conditionally released under bond pending determination of admissibility. If it is determined that such products do not meet US requirements, and the product is not treated or disposed of in accordance with US laws and regulations, Customs assesses liquidated damages under the terms of the bond. Customs' current policy is to set a bond amount that is "not less than three times the total entered value of the merchandise" (Customs Directive 099 3510-004, July 23, 1991). In August 1999 Customs proposed a rule that would provide for the assessment of liquidated damages equal to the domestic value of the merchandise. While we support the need to increase bonds as a deterrent to unscrupulous importers, determining full domestic value may be difficult. Thus it would be simpler to provide for a range of bond requirements as multiples of the entered value, e.g., 3-9 times the entered value. However, we believe that bond requirements above the current level should not be applied to importers who have in the past complied with Customs requirements. Higher bond values could be applied when an importer has failed to hold product until FDA release, failed to redeliver product, or otherwise failed to comply with Customs' requirements, particularly when the importer has a history of violations.

6. Enhance enforcement against violations of United States laws related to the importation of foods, including through the imposition of civil monetary penalties.

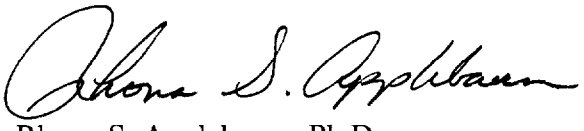
Customs has the authority to impose monetary penalties. FDA and Customs should develop guidance outlining when such penalties would be applied and provide for an appeal process.

CONCLUSIONS

The vast majority of food imported into the US complies with all US regulations and is safe and unadulterated. However, it is important that we implement appropriate control procedures to prevent unsafe and adulterated foods from entering the country and provide penalties for importers who attempt to circumvent the system. NFPA believes that the development of a process in which FDA and Customs work together to address situations in which importers violate US laws is long overdue. Thus in general we support the actions outlined in this status report. We plan to review the proposed guidance documents and regulations as they are made available.

Thank you for the opportunity to comment on this important issue.

Sincerely,



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